COPY FOR IB

PCT/KR2005/000066

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
JANG, Seongku

19th Fl., KEC Building, #275-7, Yangjae-dong, Seocho-ku
Seoul 137-130 Republic of Korea

2/7

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**29 APRIL 2005 (29.04.2005)**
Applicant's or agent's file reference PCA50103-HMY	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/KR2005/000066	**10 JANUARY 2005 (10.01.2005)**	09 JANUARY 2004 (09.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 9/16

Applicant

HANMI PHARM. CO., LTD. et al

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon 302-701,
Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
Yoon, Kyung Ae
Telephone No. 82-42-481-5605

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2005/000066

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material
   - ☐ a sequence listing
   - ☐ table(s) related to the sequence listing

   b. format of material
   - ☐ in wirtten format
   - ☐ in computer readable form

   c. time of filing/furnishing
   - ☐ contained in the international application as filed.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2005/000066

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations :

The present invention relates to cefuroxime axetil granules comprising non-crystalline cefuroxime axetil solid dispersant, sucrose fatty acid ester, methacrylic acid-ethylacrylate copolymers and a disintegrant, and a process for preparing thereof.

The following documents have been considered for the purpose of this report:
D1 = US 6107290 (22. 08. 2000)
D2 = US 4865851 (12. 09. 1989)
D3 = US 4994576 (19. 09. 1991)
D4 = US 5013833 (07. 05. 1991)

1) Novelty

D1 discloses a non-crystalline cefuroxime axetil solid dispersant comprising cefuroxime axetil, a surfactant and a water-insoluble inorganic carrier.

D2 discloses a composition comprising cefuroxime axetil in particulate form, the particles being provided with integral coatings of a lipid or a mixture of lipids which serve to mask the bitter taste of cefuroxime axetil upon oral administration.

D3 discloses a process for the preparation of a highly pure cefuroxime axetil in amorphous form which comprises preparing a highly pure solution of cefuroxime axetil and roller drying said solution.

D4 discloses a process for the preparation of a highly pure cefuroxime axetil in substantially amorphous form which involves the recovery of the product from a solution thereof by spray drying techniques.

(Continued on Supplemental Sheet)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box V.

Although the documents D1-D4 describes a composition comprising cefuroxime axetil to mask the bitter taste or improve the bioavailability of cefuroxime axetil, none of the cited documents discloses cefuroxime axetil granules comprising non-crystalline cefuroxime axetil solid dispersant, sucrose fatty acid ester, methacrylic acid-ethylacrylate copolymers and a disintegrant. The subject matter of claims 1-8 can therefore be regarded as novel under PCT Article 33(2).

2) Inventive step

There is no indication in cited documents which would have led the skilled person to use a sucrose fatty acid ester and methacrylic acid-ethylacrylate copolymers in the preparation of cefuroxime axetil granules. Also, it could not be foreseen from the cited documents that the advantage such as masking the bitterness of cefuroxime axeteil and high bioavailability can be obtained as disclosed on examples of the present invention. Therefore, the subject-matter of claims 1-8 is considered to involve an inventive step under PCT Article 33(3).

3) Industrial applicability

The subject-matter of claims 1-8 appears to be industrially applicable under PCT Article 33(4).

COPY FOR IB

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PATENT COOPERATION TREATY

REC'D 10 MAY 2005
WIPO PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

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Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-5605

Form PCT/ISA/237 (cover sheet) (January 2004)

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/KR2005/000066

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

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	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations :

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3) Industrial applicability

The subject-matter of claims 1-8 appears to be industrially applicable under PCT Article 33(4).